REMARKS/ARGUMENTS

This document responds to the office action mailed on January 5, 2010.

This is the fifth different substantive rejection of this application based on various combinations of references. On the most recent two occasions, subsequent office actions have noted that the Applicant's arguments were persuasive, withdrew the extant rejection, and then applied a new ground of rejection. The current rejection is again "non-final." The fact that the Patent Office has struggled mightily with five different rejections and combinations of prior art in and of itself is a powerful statement that the claimed subject matter is not obvious.

In the current office action, claims 1-3 and 5-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,549,672 to Maddock et al. (hereinafter "Maddock") in view of U.S. Patent No. 4,670,007 to Wheeldon et al. (hereinafter Wheeldon). Claim 4 was rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Maddock in view of Wheeldon as applied to claim 1, and further in view of U.S. Patent No. 6,319,221 to Savage et al. (hereinafter "Savage"). Reconsideration of these rejections, as they might apply to the original and amended claims in view of these remarks, is respectfully requested.

Once again, however, the cited references (a) fail to teach elements of the claimed embodiments and (b) teach away from the claimed embodiments.

Claim Rejections of Claims 1-3, 5-18 -- Under 35 U.S.C. § 103

Claims 1-3 and 5-18 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Maddock in view of Wheeldon. Applicant respectfully traverses this rejection because Maddock and Wheeldon, alone and in combination, fail to teach all of the elements of the claims.

In rejecting the claims, the office action appears to assert that the combination of Maddock and Wheeldon teach all of the elements of claim 1. *Office Action 1/5/10*, p. 2-3. Applicant respectfully disagrees. Maddock and Wheeldon disclose systems where the speed of a pump and volume of fluid being delivered have a relationship that is important to the operation of their respective systems. In contrast, claim 1 is directed to a system where the speed of a pump is independent of a calculated volume of fluid delivered, and calculation of the volume of fluid delivered is independent of the speed of the pump.

Claim 1 recites, *inter alia:*

> . . .
> a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered for the surgical procedure, wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time; and
> . . .

Maddock and Wheeldon fail to teach at least these features of claim 1.

As noted in the office action, Maddock describes a system for filling mammary prostheses and tissue expanders. *See Maddock*, col. 2, lns. 40-41. The pumping system delivers flow at a desired flow rate or pressure through a tube to an injection needle used to fill the inflatable mammary prosthesis or the tissue expander. *See id.* col. 2, lns. 42-48. The pumping system may include fluid volume measuring capabilities. *See id.* Maddock teaches that "the volume of the inflation fluid pumped by the pump is directly proportional to the total rotation of the pump head." *Maddock*, col. 5, lns. 64-66. Maddock does not describe the use of "a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered for the surgical procedure, wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time," as recited in claim 1.

The office action appears to acknowledge Maddock's failure to teach a processor and strain gauge. *Office Action 1/5/10*, p. 3, para. 5. The office action relies on Wheeldon to allegedly show these features. As argued in a previous response, Wheeldon does not provide for a processor, "wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time," as recited in claim 1. The Wheeldon system includes a processor and a weight sensing device that are used in calculating the actual flow rate of fluid being delivered intravenously to a patient.[1] If the actual

[1] As the office action suggests, Wheeldon does speak of the deficiencies (e.g., inaccuracies) in attempting to derive a fluid volume from the speed (e.g., rotations) of a peristaltic pump. To that extent, the office action may be correct that it may be obvious to substitute Wheeldon's system for Maddock. But the addition of Wheeldon does not disclose or render the claimed embodiments obvious. While Wheeldon teaches that volume cannot be accurately derived from the peristaltic pump, Wheeldon uses volume (derived from the reservoir) to control the speed of the pump. The same inaccuracies would apply, albeit in reverse, i.e., controlling the rotations of the pump. (See the lengthy discussion of assumptions, feedback, etc. that are required in

flow rate differs from the desired flow rate, output from the processor will adjust the speed of the pump. As stated in Wheeldon:

> the signals supplied by the weight sensing device 2 are processed with respect to time by the CPU 30 to produce data identifying the actual fluid delivery rate and *the CPU then compares this actual delivery rate data with the selected rate data and regulates the motor sped [sic]*, when the actual delivery rate does not correspond with the selected delivery rate, in order to eliminate the error.

Wheeldon, col. 8, lns. 18-25 (emphasis added). Wheeldon thus fails to teach a processor "wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time." Accordingly, even if a person of ordinary skill in the art would be motivated to modify Maddock to include the system of Wheeldon (although Applicant does not concede this), the resulting system would not include "a processor for processing the electrical output from the strain gauge from time-to-time to determine the volume of fluid delivered for the surgical procedure, wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time," as neither reference teaches this feature. For at least this reason, the combination of Wheeldon and Maddock do not render claim 1 obvious.

Claim 1 additionally recites, "a pump . . . for delivery of the sterile fluid at a rate within the range of 30 ml/min to 1000 ml/min." The office action appears to indicate that the pump disclosed in Maddock is inherently operated within the claimed flow rate range. Applicant notes that "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *Inherency, however, may not be established by probabilities or possibilities*. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" MPEP § 2112 (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (emphasis added)).

Wheeldon commencing at column 7, line 54. This discussion does not appear to take into account the characteristics of the fluid, the size, type, and nature of the tubing, etc.) In summary, both the Maddock and Wheeldon references link volume and pump speed in one form or another. The approach in the present application is completely different in divorcing the two parameters, i.e., fluid volume transferred and pump speed. That cannot be derived from the cited references. Both references teach away from the claimed approach.

The mere possibility of the pump disclosed in Maddock operating at the claimed rates does not inherently establish that those rates are used. Indeed, the devices shown in Figures 1-7 of Maddock all have reservoirs with a pressurized cuff that squeezes the fluid out of the fluid reservoir through the tubing. These enhanced drip systems could reasonably be interpreted to have low flow rates. Nevertheless, Maddock uses the term "fast" to describe all the disclosed embodiments. Maddock does not indicate that the embodiment with the peristaltic pump (i.e., Figure 8) is faster than the pressurized systems in the other embodiments. It is therefore possible that Maddock's pump operates at flow rates that are significantly less than the claimed flow rates. To establish inherency "The examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP § 2112 (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). Maddock does not provide enough information to indicate that the disclosed pump necessarily operates within the claimed flow rate range, and therefore the office action has not met the burden of establishing inherency with respect to his feature of claim 1.[2]

Wheeldon also fails to describe flow rates that are within the range recited in claim 1. For this additional reason, the combination of Maddock and Wheeldon fails to teach all of the elements of claim 1. For at least the reasons noted above, claim 1 as currently pending is patentable over the combination of Maddock and Wheeldon.

Applicant furthermore disagrees with the office action's assertion that "it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Maddock to include a volume monitoring system of Wheeldon (including a strain gauge and processor) because Wheeldon teaches that using a strain gauge is preferable to simply monitoring the RPM of the pump because it allows for better control and accuracy and eliminates variables such as tubing performance." *Office Action 1/5/10*, p. 3, para. 5. This statement ignores specific teachings in Maddock that indicate that a peristaltic pump provides the necessary accuracy. Indeed, Maddock states "The embodiment of FIG. 8, or other similar embodiments, are advantageous in that the peristaltic pump provides an accurate measure of the

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[2] There are many versions of peristaltic pumps. It is not proper to use Applicant's specification for the proposition that the speed of the peristaltic pump selected by applicant and claimed in this application is inherent in the prior art.

volume delivered so that accurate partial delivery of the fluid within container 20 may be achieved." *Maddock*, col. 6, lns. 34-38. This statement is a specific teaching away from modifying the volume measuring system of Maddock, namely the peristaltic pump because as noted by Maddock "the peristaltic pump provides an accurate measure of the volume delivered." *Id.* Accordingly, Maddock teaches away from modifying its use of a peristaltic pump.

The combination of Maddock and Wheeldon thus fails to teach all of the elements of claim 1, and furthermore Maddock teaches away from modifying its use of a peristaltic pump. Claims 2-9 depend upon claim 1 and are allowable for at least the same reasons.

Independent claim 10 is directed to "a method for rapidly delivering and accurately monitoring the delivery of a desired volume of sterile fluid to a targeted anatomical site or implantable device." Claim 10 includes features similar to claim 1. Specifically, claim 10 provides for "processing with a processor the electronic signal from the strain gauge to display the volume of sterile fluid removed from the container from time-to-time, wherein output from the processor is not electronically connected to the pump and wherein the processor does not adjust the speed of the pump at any time." These features are not taught or suggested by the combination of Maddock and Wheeldon. The combination of Maddock and Wheeldon thus fails to teach all of the elements of claim 10 and indeed Maddock teaches away from modifying its use of a peristaltic pump. Claims 11 and 13-15 depend upon claim 10 and are allowable for at least the same reasons.

Claim Rejections of Claim 4 -- Under 35 U.S.C. § 103

Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock in view of Wheeldon as applied to claim 1, and further in view of Savage. Claim 4 depends upon independent claim 1 and includes all of the features recited in claim 1. Applicants traverse the rejection because the cited references do not teach all of the features of claim 4.

Savage describes systems and methods of measuring fluid retention of a patient. *See Savage*, col. 2, ln 1. Savage teaches that the fluid retention or loss of a patient is determined by weighing fluid introduced into the patient to produce a fluid-in amount, weighing fluid collected from the patient to produce a fluid-out amount, and calculating a difference between the fluid-in amount and the fluid-out amount with the difference representing the fluid retention or loss of the patient. *See id*, col. 2, lns. 1-7. Savage, even in combination with Maddock and Wheeldon,

does not teach all of the elements of claim 4. Claim 4 is therefore allowable over the combination of Maddock, Wheeldon, and Savage.

Conclusion

This document responds to the office action mailed on January 5, 2010. Still, the office action may contain arguments and rejections that are not directly addressed by this document because they are rendered moot in light of the preceding arguments in favor of patentability. Hence, failure of this document to directly address an argument raised in the office action should not be taken as an indication that the Applicant believes the argument has merit. Additionally, failure to address statements/comments made in the office action does not mean that the Applicant acquiesces to such statements or comments. Furthermore, the claims of the present application may include other elements, not discussed in this document, which are not shown, taught, or otherwise suggested by the art of record. Accordingly, the preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability.

No additional fees are believed due with this response. However, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment with respect to this patent application to deposit account number 13-2725.

In light of the above remarks, it is believed that the application is now in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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/René A. Pereyra/

René A. Pereyra, Reg. No. 45,800
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
303.357.1637